K00 3613

APR - 3 2001

GE Medical Systems

P.O. Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter
  Larry A. Kroger, Ph.D., 262-544-3894, November 21, 2000

- Identification of the Product
  3.0T Signa VH/I Transmit/Receive (T/R) Body Imaging Coil

  Manufacturer Address: GE Medical Systems
  3200 N. Grandview Blvd.
  Waukesha, WI 53188

- Marketed Devices
  The 3.0T Signa VH/I T/R Body Imaging Coil is substantially equivalent to the currently marketed Transmit/Receive Body Imaging Coil on the Signa CV/i MR System.

- Device Description
  The 3.0T Signa VH/i Body Imaging Coil is a transmit and receive birdcage RF design. It is designed for use with a horizontal magnetic field MR imaging system.

- Indications for Use
  The Indications for use for the 3.0T Signa VH/*i* T/R Body Imaging Coil expands the imaging capability of the 3.0T Signa VH/*I* MR Imaging System. The T/R Body Imaging Coil is intended for imaging the Neck, Spine, Abdomen/Thorax and the extremities.

- Comparison with Predicate
  The 3.0T Signa VH/i T/R Body Imaging Coil is similar to the Transmit/Receive Body Imaging Coil on the currently marketed Signa CV/i MR System except that its length dimension is different and it is tuned to resonate at 3.0T frequencies.

- Summary of Studies
  The 3.0T Signa VH/i T/R Body Imaging Coil was evaluated to the appropriate NEMA performance standards. The coil was evaluated to the international safety standards IEC 601-1 and IEC 601-2-33 and performed to stated specifications.

- Conclusions
  It is the opinion of GE that the 3.0T Signa VH/I T/R Body Imaging Coil is substantially equivalent to the presently marketed Transmit/Receive Body Imaging Coil on the Signa CV/I MR System. This coil does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2001

Mr. Clyde Krumrai
Magnetic Resonance Systems
GE Medical Systems
PO Box 414, W-827
MILWAUKEE WI 53201

Re: K003613
T/R Body Imaging Coil for 3.0T Signa VH/i
Dated: February 13, 2001
Received: February 14, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 MOS

Dear Mr. Krumrai:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K00 3613

Device Name: 3.0T Signa VH/*i* Transmit/Receive Body Imaging Coil
Indications For Use:

The Indications for use for the 3.0T Signa VH/*i* Transmit/Receive Body Imaging Coil expands the imaging capability of the 3.0T Signa VH/*i* MR Imaging System.

The Transmit/Receive Body Imaging Coil is intended for imaging the Neck, Spine, Abdomen/Thorax and the extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seger

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003613

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)